Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 18-46 are pending in the application, with18, 22, 26, 29 being the independent claims. Claims 18, 22, 26, 29, and 31 are sought to be amended. Claims 35-46 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

The foregoing amendment has been made to overcome the Office Action and to place the claims in better condition for Appeal.

Support for the amendment to claims 18, 22, 26 and 29 may be found in the claims as originally filed and in the specification at page 2. Page 2 of the specification discusses silica particle size, surface area and weight percent range of tocopherols in this invention, and describes this invention as a vitamin powder wherein tocopherol are present in amounts greater than 50 to about 80 weight percent.

Additionally, Applicants' specification, which describes the invention as a whole, does not include fatty acid esters of glycerine in the vitamin composition. There is nothing to indicate, nor is it necessary, that fatty acid esters of glycerine need to be added to obtain the free-flowing vitamin powders as described by Applicants. *See In Re Johnson*, 194 USPQ 187 (CCPA 1997) (Stating that it is permissible under 35 U.S.C. §112 to add a proviso excluding a prior art reference without express exclusion in the specification, as applicant is *claiming less* than the full scope of his disclosure.); *see also* MPEP §2173.05(i) *citing Ex parte Parks*, 30 USPQ 2d 1234, 1236 (Bd. Pat. App. & Inter. 1993) "the observation of a lack of literal support does not, in and of itself, establish a prima facie case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112).

Support for the amendment of claim 31 may be found at page 7, Example 6. Example 6 discusses a small loss of tocopherol over 11 months without special protection from light or air.

Support for the addition of claims 35- 46 may be found at page 7, Example 6. Example 6 discusses a small loss of tocopherol over 11 months without special protection from light or air.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Rejections under 35 U.S.C. § 102

The Examiner rejected claims 18, 19, 26, 27, 29, and 30 under 35 U.S.C. § 102(b) as being anticipated by Hobbs *et al.* (U.S. Patent No. 5,234,695). Applicants respectfully traverse this rejection.

MPEP § 2131 describes the application of 35 U.S.C. § 102(b). A claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131 *citing Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). While only one reference should be used in making a rejection under § 102, the use of multiple references has been held to be proper when the extra references are cited prove an enabling disclosure, explain the meaning of the term, or show that a characteristic that is not disclosed in the reference is inherent. *Id.*

The Examiner, in maintaining the rejection against these claims, pointed to the teaching of Hobbs *et al.* that vitamin can be present between 10 and 80 weight percent in the vitamin E composition. Applicants agree. However, Hobbs *et al.* also teach that the vitamin E composition comprises at least one fatty acid ester of glycerine as an essential ingredient (see abstract and column 2, lines 16-18). Applicants have amended independent claims 18, 22, 26, and 29 to exclude the presence of fatty acid esters of glycerine. Claims 19 and 27 depend from claims 18 and 26, respectively. Claim 30 depends from claims 18, 22, or 26. Applicants' composition does not contain any fatty acid esters of glycerine. The absence of fatty acid esters of glycerine from the composition is not taught by Hobbs *et al.* Therefore, Hobbs *et al.* does not teach every limitation of the Applicants' invention. Applicants submit that the rejection of claims 18, 19, 26, 27, 29 and 30 under 35 U.S.C. § 102(b) has been overcome by amendment and should be withdrawn.

II Rejections under 35 U.S.C. § 103

A. Schmidt et al. (U.S. Patent No. 4,486,435)

The Examiner rejected claims 18-28, and 31-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,486,435 ('435 patent) to Schmidt *et al.* Applicants respectfully traverse this rejection.

The Examiner asserts that although Schmidt *et al.* do not teach that the vitamin is specifically mixed tocopherol, they do teach that the vitamin can be selected from a group including vitamin E. The Examiner then points to Applicants' specification which describes that vitamin E is a mixture of different molecular species which vary based on the natural

variation in the oil. Finally, the Examiner asserts that based on Applicants' own admission, Schmidt's teaching of vitamin E suggests the limitations of the instant claims.

The Examiner next asserts that although Schmidt *et al.* do not teach the specific density and surface area for the silica as claimed by Applicants, it is the position of the Examiner that with respect to particular silica particle size, absent a clear showing of criticality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of optimization. The Examiner then shifted the burden to Applicants to show why the difference in particle size or surface area renders a different result.

The '435 patent teaches encapsulated vitamin powders coated with a hydrophobic silica with improved free-flowing properties (see abstract). The '435 patent states, "of critical importance in the preparation of the vitamin powders of the invention is the utilization of ultrafine particle size materials which are capable of coating the partially dried, encapsulated vitamin components" (column 3, lines 12-15). The '435 patent then defines the ultrafine particle size of the coating material to be about 0.01 to 0.04 microns (column 3, lines 33-37). Thus, it is of critical importance that the hydrophobic silica of the invention of the '435 patent has a particle size between 0.01 to 0.04 microns. Since the '435 patent teaches that it is critical to have ultrafine particles between 0.01 to 0.04 microns, it would not have been within the skill of one of ordinary skill in the art to optimize beyond this critical range. The silica of the Applicants' invention has a particle size of between 40 and 50 microns, which is clearly outside the critical range taught by the '435 patent. The silica of Applicants' invention would not have qualified as "ultrafine" as defined by the '435 patent and therefore, would not have been an obvious choice in the preparation of vitamin powders.

Therefore, claims 18-28 are not obvious in view of the '435 patent and Applicants respectfully request withdrawal of this rejection.

The Examiner also asserts that although Schmidt *et al.* do not specifically discuss stability, that absent evidence to the contrary, the formulation must provide appropriate stability, or it would be useless for it's intended purpose. The burden was then shifted to the Applicants to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. Applicants have amended the claims in view of the Examiner's comments. Claim 31, which discusses stability, has been amended to depend from claim 18. Thus, the limitation that the composition remains stable for at least 11 months is now a further limitation of claim 18, which is unobvious for reasons Applicants stated previously. Claims 32-34 depend from claim 31, therefore claims 31-34 are not obvious in view of the '435 patent. Claims 35-38, 39-42, and 43-46 have been added to limit independent claims 22, 26, and 29 respectively with regard to the stability of the claimed invention, and therefore are also unobvious. Withdrawal of this rejection is respectfully requested.

Lastly, the Examiner asserts that Applicants' claimed range of about 65-80 weight percent of vitamin does not show a patentable distinction over the reference, which states that the vitamin can be present at about 60 weight percent. The Examiner then shifted the burden to the Applicants to show unexpected results and patentable distinctions between the instant claims and the prior art. The Examiner concludes that one of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E, silica, and corn starch, based on the teachings of Schmidt with expected result being a free-flowing, non-sticking powder useful for pharmaceutical formulations.

Although Applicants have amended the claims to once again specify that the vitamin content in the composition is at least about 50 to about 80%, this distinction is not relied upon by Applicants to overcome this obviousness rejection. The particle size requirement discussed above is a patentable distinction over the prior art, therefore Applicants respectfully submit that the rejection of claims 18-28 and 31-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,486,435 to Schmidt *et al.* has been overcome and should be withdrawn.

B. Schmidt et al. (U.S. Patent No. 4,603,143)

The Examiner rejected claims 22-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,603,143 ('143 patent) to Schmidt *et al.* Applicants respectfully traverse this rejection.

The Examiner, in maintaining the rejection of these claims, pointed to the '143 patent, which discloses vitamin active powders of a composition which comprises at least one fat-soluble vitamin material and a silicon containing material (column 1, lines 38-45). The silicon dioxide used in their composition has a density of around 0.2g/cc (which is equivalent to 12.5 lbs./cu. ft.), and a particle size which passes through a 100 mesh sieve (columns 3-4, table 1). (A 100 mesh sieve allows only particles which are smaller than 150 microns to pass through). The Examiner asserts that although the '143 patent does not teach the specific particle size for the silica, it does teach that the particles are smaller than 150 microns and that determination of particle sizes from within a broad range is within the skill of the ordinary worker as part of normal optimization. The burden was then shifted to the

Applicants to show that the silica disclosed by the '143 patent does not possess the same characteristics as the silica claimed by the Applicants.

Although the '143 patent does not teach specific silicon dioxide particle size, it does teach agglomerates of silicon-containing material in which 50% of the total have a minimum length, width, or both of 300 microns (see Abstract). As stated in the '143 patent, "for the purposes of this invention disclosure, any agglomerate which has a particle size of less than 50 microns is not counted in the total when determining whether 50% of the total number of agglomerates has a minimum length, width, or both of 300 microns" (column 2, lines 15-20). Although the agglomerate is said to consist of silicon-containing material, silicon dioxide is said to be the primary component, with no other materials specified (column 1, lines 62-63). One of skill in the art would have no choice but to presume that if the non-silica material(s) in these agglomerates are of any importance, they would certainly be specified. No such data is provided by the '143 patent, thus Applicants understand these agglomerates to be 100% silica.

These silica agglomerates are described as *essential* (emphasis added) to obtaining a free-flowing, fat soluble vitamin containing powder having improved stability (column 1, lines 46-50). These properties are thought to result from the use of the specific silicon-containing particulate materials (column 3, lines 35-41). Applicants' invention claims silica which has a particle size of between 40 and 50 microns, but does not require an agglomerate of silicon-containing material of a size greater than 300 microns. Therefore, the '143 patent teaches away from Applicants' invention, relying on greater particle size for increased stability.

Applicants assert that the present invention has supplied the function of the omitted agglomerates by a different structure- one which does not require agglomerates as described in the '143 patent. No such agglomerates are required in Applicants' invention. Instead, silica particles of within the size range of 40-50 microns are used to produce the vitamin powders of the Applicants' claimed invention. Omission of the agglomerate described in the '143 patent, while retaining the function of the current invention has overcome a finding of obviousness by the Examiner. *See In re Anthony et al.*, 32 CCPA 868, 147 F.2d 695, 64 USPQ 553; *See also In re Edge,* 53 CCPA 1124, 359 F.2d 896 (Stating it may unobvious to omit an element while retaining that element's function with a different structure.) One of ordinary skill in the art would not have been motivated to make a vitamin power without using a silicon-containing agglomerate of greater than 300 microns in view of the '143 patent because it would be unexpected that the smaller size would import improved stability. Therefore, withdrawal of this rejection is respectfully requested.

The Examiner advanced the position that the formulation taught by the '143 patent must provide appropriate stability, or it would be useless for its intended purpose and shifted the burden to the Applicants to prove that the claimed products are functionally different than those taught by the prior art. Applicants contend that this rejection has been overcome by amending claim 31 to depend from 18. Claims 31-34 are further limitations of claim 18, which is unobvious for reasons stated previously. Applicants respectfully submit that rejection of claims 22-34 under 35 U.S.C. § 103(a) as being unpatentable over the '143 patent has been overcome and should be withdrawn.

C. Hobbs et al. (U.S. Patent No. 5,234,695)

The Examiner rejected claims 18-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,234,695. Applicants respectfully traverse this rejection.

Hobbs *et al.* teach a vitamin E composition comprising a free flowing powder containing between 20-60% of vitamin E compound and at least one flow agent selected from a group including silicon dioxide and starch. It is the position of the Examiner that although Hobbs *et al.* do not teach that the vitamin is specifically mixed tocopherols, they do teach that the vitamin can be selected from a group including vitamin E. Based on Applicants' description of vitamin E as a mixture of different molecular species which vary based on the natural variation of the oil (Applicants' specification, p.3, lines 24-27), the Examiner concluded that Hobbs' teaching of vitamin E suggests the limitation of the claims.

The Examiner also asserted that with respect to the particular silica particle size, absent a clear showing of cruciality, the determination and manipulation of particular sizes is within the skill of the ordinary worker as part of the process of normal optimization. The burden was then shifted to the applicant to show why the difference in particle size or surface area rendered a different result.

Applicants submit that these rejections have been overcome by amendment to claims 18, 22, 26 and 29 which limit Applicants' invention to exclude fatty acid esters of glycerine. Claims 19 and 27 depend from claims 18 and 26, respectively. Claim 30 depends from claims 18, 22, or 26. Hobbs *et al.* teach that the fatty acid ester of glycerine is an *essential* (emphasis added) component of the vitamin E composition therein claimed (see Abstract). To exclude fatty acid esters of glycerine, as Applicants have, is in stark contrast to the

teaching of Hobbs *et al,* therefore Applicants' free-flowing vitamin powder excluding fatty acid esters of glycerine is not obvious.

The Examiner also addressed the issue of stability of the vitamin compound. It was the position of the Examiner that a formulation must provide appropriate stability, or it would be useless for it's intended purpose. Again, the burden was placed upon the Applicants to prove that the claimed products are functionally different than those taught by the prior art. Claims 31-34, which relate to the stability of the composition, have been amended to depend from claim 18, which is unobvious for reasons Applicants stated above.

Lastly, the Examiner maintains an obviousness rejection based on the vitamin weight percent ranges claimed by applicant over those of Hobbs *et al.* Applicants provided ranges in the claims to recite "at least 65 to about 80 weight percent of at least one vitamin," while the reference teaches only 60 weight percent of vitamin. The burden was shifted to Applicants to show patentable distinctions between 60% and 65%.

Applicants submit that this rejection has been overcome by amendment to claims 18, 22, 26 and 29 to exclude fatty acid esters of glycerine. Hobbs *et al.* teach that a fatty acid ester of glycerine is a necessary component of the invention. One of skill in the art would not be motivated to remove an essential element from the vitamin composition, in view of Hobbs *et al.*, because it would render the invention non-functional for it's intended purpose. Applicants submit that the rejection of claims 18-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,234,695 to Hobbs *et al.* has been overcome by excluding fatty acid esters of glycerine from the claimed invention and should be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

18. (Twice Amended) A composition comprising about 5 to about 34 weight percent redried cornstarch, silica and [at least 65 to about 80 weight percent of] at least one vitamin, wherein said silica has a particle size of between 40 and 50 microns and said composition is free of fatty acid esters of glycerine.

22. (Once Amended) A composition comprising silica and at least one vitamin, wherein said silica has a density of at least 12.5 lbs/cu. ft., a particle size of between 40 and 50 microns, a surface area of from about 400 m^2/g to 500 m^2/g, and said composition is free of fatty acid esters of glycerine.

26. (Twice Amended) A composition comprising silica and at least one vitamin, wherein said vitamin is present in amounts from about [65 to about 80] 50 to about 80 weight percent, [wherein] said silica has a particle size of between 40 and 50 microns, and said composition is free of fatty acid esters of glycerine.

29. (Twice Amended) A composition prepared according to the method comprising mixing silica and liquid mixed tocopherols, wherein said liquid mixed tocopherols are present in amounts of 65 to about 80 weight percent of said vitamin powder, [and] said silica has a particle size of between 40 and 50 microns, and said composition is free of fatty acid esters of glycerine.

31. (Once Amended) [A] The dry, free-flowing vitamin composition of claim 18, wherein said composition is stable at room temperature for at least 11 months.

Claims 35-46 have been added.